

### Remarks/Arguments

According to the Office Action, Claims 39-43 are pending in this application. Claim 39 has been amended for clarity. Although some prior rejections were withdrawn, all claims remain rejected under 35 USC 112, first paragraph for lack of enablement. The rejection is respectfully traversed.

#### Rejections under 35 USC § 112, first paragraph - enablement

Claims 39-43 were rejected under 35 USC 112, first paragraph, for lack of enablement. The Examiner says that "since the *in vitro* evidence provided is not predictive of an *in vivo* effect and since no conditions are known for which PRO335 could be used, it would require undue experimentation for the skilled artisan to use the invention." Applicants respectfully traverse this rejection.

Utility has been asserted for PRO335 as an immunostimulator for use in the treatment of diseases benefiting from the enhancement of immune response such as AIDS and further, for antagonists of PRO335 as immunosuppressors in graft-vs-host disease, autoimmune disease, etc. based on the positive result in an MLR assay. This utility pertains to the field of immunotherapy. The Examiner states that the MLR assay is not predictive of *in vivo* efficacy, and hence undue experimentation would be needed to use the invention. Applicants respectfully disagree. Just because experimentation maybe needed to practice the invention, such experimentation is not necessarily undue, and further, it does not mean that the art of immunotherapy as a whole is unpredictable. In fact, Applicants submit that the level of skill in the art of immunotherapy is very advanced that the skilled artisan would find that the experimentation needed in this instance, routine. In *In re Wands*, the courts concluded that the amount of experimentation needed was not undue in view of the direction and guidance provided by the Appellants and the level of skill in the art:

"the court held that ....there was 'considerable direction and guidance' in the specification; there was 'a high level of skill in the art at the time the application was filed;' and all the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406; M.P.E.P. 2164.01(a)

Based on the positive MLR result of PRO335, Applicants' have provided a set pathway for experimentation, namely, to evaluate whether PRO335 or its antagonists can be used *in vivo* for immune related conditions. While this involves experimentation, Applicants assert that this amount is not undue. In this regard, Applicants respectfully remind that the skilled artisan in the field of Immunology and Immunotherapeutics at the effective filing date (September 17, 1998), would likely be a person with a Ph. D. or M.D. degree, sometimes both and with extensive experience. Such a person would, in fact, find it routine to carry out *in vivo* analysis to determine whether PRO335 or its antagonists are useful in *in vivo* immune diseases, based on such directed guidance.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

All claims pending in this application are believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any additional fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C47).  
Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: March 2, 2004

  
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